

**REMARKS**

Reconsideration of this application is respectfully requested.

Upon entry of the foregoing amendment, claims 65-69, 73-76, 79, 82-87, 90-103 are pending in the application. New claims 92-103 are added. Claims 70-72, 77-78, 80-81 and 88-89 are canceled without prejudice to or disclaimer of the subject matter therein. Claims 65-69, 73-74, 76, 79, 82-84, 86-87 and 91 are amended.

Applicants respectfully request entry of the above amendment and submit that the above amendment does not constitute new matter.

Support for the amendments to the claims and new claims can be found throughout the specification and in the claims as originally filed. In particular, support for the amendments can be found, *inter alia*, in the specification at page 3, ll. 32-33; page 4, l. 29, page 7, ll. 34-35; page 8, ll. 7-8; and page 5, ll. 26-28.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

**Claim Objections**

The Office Action states that claim 65 is objected to on the basis that it "lacks the intended use (e.g., for oral administration) of the claimed composition." (Office Action of May 5, 2004, page 2.) Applicants have amended claim 65 to include the recitation "for oral administration," thereby rendering the objection to claim 65 moot.

The Office Action states that claim 75 is objected to on the ground that "xanthofyll" is misspelled. Applicants have amended claim 75 to correct the spelling to "xanthophyll." Thus, the objection to claim 75 has been rendered moot.

The Office Action states that claim 68 is objected to; however, no reason is provided for the objection to claim 68. Thus, Applicants assert that no reason exists for objecting to claim 68 and that it is in proper form. However, in the event that the reason for the objection to claim 65 also applies to claim 68, which depends from claim 65, the objection to claim 68 has been rendered moot by the amendment to claim 65.

Consequently, Applicants respectfully request that the objection to claims 65, 68 and 75 be withdrawn.

**Rejections under 35 U.S.C. § 112, first paragraph**

The Office Action states that claims 65-69, 71, 73-76 and 78-91 are rejected under 35 U.S.C. § 112, para. 1, for allegedly failing to comply with the enablement requirement. The Office Action states that "the specification, while enabling for preparing a 'grape seed extract', does not reasonably provide enablement for preparing a 'cartilage extract', 'fish extract', 'plant extract' or 'tomato Extract'." (Office Action of May 5, 2004, pages 2-3.)

Amended claim 65 no longer contains the terms "cartilage extract" or "tomato extract." Thus, the rejection of claim 65 for lack of enablement has been rendered moot. Accordingly, the rejection of claims 66-69, 73, 75-76, 79, 82-83, 85 and 90-91 which depend directly or indirectly from claim 65 and also do not contain the terms "cartilage extract" or "tomato extract", has also been rendered moot.

Amended claims 86 and 87 no longer contain the term "fish extract." Thus, the rejection of claims 86 and 87 based on lack of enablement has been rendered moot.

Claims 71, 78, 80-81 and 88-89 have been canceled, thereby rendering the rejection of these claims based on lack of enablement moot.

Regarding claims 74 and 84, Applicants respectfully submit that one of skill in the art would know the various methods of extraction from natural sources and possible solvents and solvent combinations suitable for practicing the subject matter covered by claims 74 and 84, which include, in claim 74, lycopene from a tomato extract, and, in claim 84, tomato extract

comprising lycopene. Thus, undue experimentation would not be required to carry out the invention of claims 74 and 84.

Consequently, Applicants respectfully request that the rejection of claims 65-69, 71, 73-76 and 78-91 under 35 U.S.C. § 112, para. 1, be withdrawn.

**Rejections under 35 U.S.C. § 112, second paragraph**

The Office Action states that claims 65-69, 71, 73-76 and 78-91 are rejected under 35 U.S.C. § 112, para. 2, as being indefinite for failure to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Applicants assert that the amendment renders moot each of the reasons for the rejection of claims 65-59, 71, 73-76 and 78-79 as purportedly indefinite. In addition, Applicants traverse the rejection of claims 74 and 84 based on alleged indefiniteness.

Amended claim 65 recites "[a] composition for oral administration comprising." In addition, amended claim 65 also no longer contains the phrases "cartilage extract," "extractable," or "obtainable." Therefore, the rejection of claim 65 on these bases has been rendered moot.

Amended claim 65 no longer contains the terms "cartilage extract" or "tomato extract." Thus, the rejection to claim 65 for alleged indefiniteness has been rendered moot. Accordingly, the rejection of claims 66-69, 73, 75-76, 79, 82-83, 85 and 90-91 which depend directly or indirectly from claim 65 and also do not contain the terms "cartilage extract" or "tomato extract", has also been rendered moot.

Amended claims 86 and 87 no longer contain the term "fish extract." Thus, the rejection to claims 86 and 87 based on alleged indefiniteness has been rendered moot.

Applicants respectfully traverse the rejection of claims 74 and 84 based on indefiniteness in the recitation of "tomato extract." One of ordinary skill in the art would clearly understand the metes and bounds of the phrases "wherein lycopene is obtained from a tomato extract," which is recited in claim 74, and "tomato extract comprising lycopene," which is recited in claim 84. A skilled artisan would know the clear delineation of the term "extract" as it relates to "tomato

extract" because a skilled artisan would understand the proper methods of extraction and possible solvents and solvent combinations in relation to tomatoes. Thus, Applicants respectfully request that this rejection of claims 74 and 84 under 35 U.S.C. § 112, para. 2, be withdrawn.

The Office Action further states that "claims 71, 80-83, 86, 89 and 90 are rendered unclear and vague because in those claims the quantities and or ratios are recited in relation to an extract and a particular chemical compound." (Office Action of May 5, 2004, page 5.) Claims 71, 80-81 and 89 have been canceled, thereby rendering the rejection of these claims based on indefiniteness moot. Applicants submit the amendments to the claims render the rejections of claims 82-83 and 86 based on alleged indefiniteness moot.

Claims 86 and 87 no longer depend from claim 65, thereby rendering the rejection of claims 86 and 87 based on indefiniteness moot.

Claim 88 has been canceled, thereby rendering the rejection of claim 88 based on indefiniteness moot.

In addition, amended claim 91 now recites "a form suitable for oral administration comprising tablets, powders, granules, capsules, sachets, solutions, suspensions, tonics or syrups, or a combination thereof." Thus, the rejection of claim 91 for allegedly being indefinite has been rendered moot.

### **Rejections under 35 U.S.C. § 102**

Claims 65-69, 73-75 and 78 are rejected in the Office Action under 35 U.S.C. § 102(b) as allegedly being anticipated by Greenberg, U.S. Patent No. 5,569,458 ("Greenberg"), with evidence provided by Bombardelli, EP 0 659 402 ("Bombardelli"). In particular, the position set forth in the Office Action is that

Since the examiner-cited reference teaches a composition comprising cartilage extract, hydrophilic antioxidants, lycopene and beta-carotene (see Column 2, Line 63) an antioxidant according to applicant's own assertion, Greenberg's composition teaches a composition comprising a cartilage extract, hydrophilic antioxidants, lycopene and beta carotene (See Column 3, Line 36

after the word "trypsin"). As discussed *supra*, Greenberg's composition inherently comprises both antioxidants because said composition is comprised of proanthocyanidins from Red wine grapes (See Column 3, Line 37) and beta carotene (i.e.,  $\beta$ -carotene)

(Office Action of May 5, 2004, page 7.) Applicants respectfully traverse this rejection.

Claim 78 has been canceled. Thus, the rejection of claim 78 under 35 U.S.C. § 102(b) has been rendered moot.

Applicants assert that anticipation can be established only by a single reference that discloses each and every element of the claimed invention. *See Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1270 (Fed. Cir. 1984); M.P.E.P. § 2131 at 2100-73 (8<sup>th</sup> ed., Rev. No. 2). If a single element required by the claim is missing in the reference, there can be no anticipation. *See Structural Rubber*, 749 F.2d at 707, 223 U.S.P.Q. at 1271-72.

Applicants submit that Greenberg does not disclose each and every element required by claims 65-69, 73-75. Independent claim 65, as amended, is directed to a composition comprising glycosaminoglycan, polyphenolic hydrophilic antioxidants and lycopene. Greenberg does not disclose a composition comprising glycosaminoglycan, polyphenolic hydrophilic antioxidants and lycopene. In particular, Greenberg does not disclose a composition comprising lycopene. Applicants assert that the citations to Greenberg set forth in the Office Action and quoted above do not teach a composition comprising lycopene.

Moreover, it is *not* the case that Greenberg "inherently comprises both antioxidants because said composition is comprised of proanthocyanidins from Red wine grapes (See Column 3, Line 37) and beta carotene (i.e.,  $\beta$ -carotene)." (Office Action of May 5, 2004.) Regarding inherent anticipation, the M.P.E.P. states:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

M.P.E.P. § 2131.01 at 2100-74 (8<sup>th</sup> ed., no. 2) (quoting *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d. 1746, 1749 (Fed. Cir. 1991).

The Office Action has not shown that lycopene is "necessarily present" in a composition described in Greenberg. Hence, the Office Action has not established that Greenberg inherently anticipates the claims of the instant invention.

Furthermore, Bombardelli, which "is cited to merely support the constituents of hydrophilic and lipophilic antioxidants and not as a prior art reference" (Office Action of May 5, 2004, page 6), does not show that lycopene is "necessarily present" in a composition disclosed in Greenberg. Although Bombardelli states "wherein the lipophilic antioxidant is selected from Vitamin E,  $\beta$ -carotene, lycopene," such a disclosure *does not* establish that a reference that discloses a formulation containing vitamin E and/or  $\beta$ -carotene (*i.e.*, Greenberg) necessarily discloses lycopene.

Accordingly, Applicants submit that any alleged argument of anticipation has been effectively rebutted because neither Greenberg nor Bombardelli with evidence provided by Bombardelli discloses each and every element of the claimed invention. Consequently, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

### **Rejections under 35 U.S.C. § 103**

The Office Action states that claims 65-85 and 88 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Greenberg in view of Stedman's Medical Dictionary (Spraycar ed. 1995) ("Spraycar"), Bombardelli and Kosbab, WO 00/07607 ("Kosbab"). In particular, it is the Examiner's position that

One having ordinary skill in the art would have been motivated to modify Greenberg's composition according to the beneficial teachings from Bombardelli et al., because Bombardelli et al., remedy the deficiency in Greenberg's teachings of distinguishing between components comprising hydrophilic and lipophilic (sic) antioxidants and indicate the natural source (plant species and extracts from those plant species) for those antioxidants. Kosbab's beneficial teachings remedy the deficiency

in Greenberg's and Bombardelli et al's teaching by beneficially teaching that cartilage and chondroitin sulphate as components of Kosbab's composition, and further that the composition is also comprised of antioxidants obtained from a variety of natural sources (e.g., plants) and that glycosaminoglycan is one of the extractable compound from cartilage.

(Office Action of May 5, 2004, page 8.) Applicants respectfully traverse this rejection,

Claims 70-72, 77-78, 80-81 and 88 have been canceled. Thus, the rejection of these claims under 35 U.S.C. § 103(a) has been rendered moot.

Applicants respectfully submit that the U.S.P.T.O. has the initial burden of establishing a *prima facie* case of obviousness. In the absence of such *prima facie* case, Applicants' claims must be allowed. In order for the U.S.P.T.O. to fulfill its burden of establishing a *prima facie* case of obviousness, the prior art reference (or references) must teach or suggest all the claim limitations. See M.P.E.P. § 2143.03 at 2100-133 (8<sup>th</sup> ed., Rev. No. 2). Applicants submit that the present invention is nonobvious over the art because the references cited in the Office Action do not teach or suggest Applicants' *claimed inventive combination*. See *Smith Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356 (Fed. Cir. 1999) (“[T]here is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time of the invention.”) (citation omitted).

Further, Applicants point out that a statement that modifications of the prior art to meet the claimed invention “would have been obvious to one of ordinary skill in the art” because the references teach that all aspects of the claimed invention were individually known in the art is *not* sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the references. See *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) *citing* *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1544 (“To imbue one of ordinary skill in the art with knowledge of the invention . . . when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of hindsight syndrome . . .”).

Applicants submit that the Office Action does not provide any objective reason to combine all four cited references- Greenberg, Spraycar, Bombardelli and Kosbab -for the obviousness rejection of claims 65-69, 73-76, 79 and 82-85. The references cited in the Office Action against these claims do not teach or suggest Applicants' claimed inventive combination. Specifically, the cited references do not teach or suggest the composition of independent claim 65, as amended, which comprises glycosaminoglycan, polyphenolic hydrophilic antioxidants and lycopene. In addition, the cited references do not teach or suggest the composition of independent claim 84, as amended, which comprises 20-40%, weight/weight, cartilage enzymatic hydrolysate comprising glycosaminoglycan; 1-10%, weight/weight, grape seed extract comprising oligomeric procyanidol; and 1-10%, weight/weight, tomato extract comprising lycopene.

Accordingly, Applicants submit that the Office Action has not established a *prima facie* case of obviousness and, therefore, Applicants have rebutted the Office Action's rejection of claims 65-69, 73-76, 79 and 82-85 based on obviousness. Consequently, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

The Office Action also rejected claims 65-85 and 88-91 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Greenberg in view of Spraycar (page 121, col. 1, lines 44-48), Bombardelli and Kosbab and further in view of Hersh, U.S. Patent No. 5,906,811 ("Hersh") and Murad, U.S. Patent No. 6,630,163 ("Murad"). In particular, it is the Examiner's position that

An artisan of ordinary skill would be motivated to combine the teachings from each one of the cited references because each one of the cited prior art references teach a composition comprising antioxidants in mixture with plant extracts, silicon, microcrystalline cellulose and inulin. Herss [sic] remedies the deficiency of Acerola extract in the composition of Greenberg et al., while Murad remedies the deficiencies of inulin, microcrystalline cellulose and silicon dioxide in teachings Greenberg et al.

(Office Action of May 5, 2004, page 10.) Applicants respectfully traverse this rejection.

Claims 70-72, 77-78, 80-81 and 88-89 have been canceled. Thus, the rejection of these claims under 35 U.S.C. § 103(a) has been rendered moot.



As discussed above, Applicants assert that in order for the U.S.P.T.O. to fulfill its burden of establishing a *prima facie* case of obviousness, the prior art reference must teach or suggest all the claim limitations. See M.P.E.P. § 2143.03 at 2100-133.

Applicants assert that the Office Action does not provide any objective reason to combine all six cited references- Greenberg, Spraycar, Bombardelli, Kosbab, Hersh and Murad -for the obviousness rejection of claims 65-69, 73-76, 79, 82-85, and 90-91. The references cited in the Office Action against these claims do not teach or suggest Applicants' claimed inventive combination. Specifically, the cited references do not teach or suggest the composition of independent claim 65, as amended, which comprises glycosaminoglycan, polyphenolic hydrophilic antioxidants and lycopene. For example, while Kosbab may disclose compositions comprising chondroitin sulphate, he does so in the context of a cancer preventative and therapeutic formula comprising numerous other ingredients. Kosbab (alone or in combination with any other reference applied in this rejection) fails to suggest the isolation of chondroitin sulphate from that formula and combination thereof with ingredients disclosed in Greenberg, Spraycar, Bombardelli, Hersh and Murad. Such a selection and subsequent combination could only be made with the impermissible hindsight provided by Applicants' disclosure. In addition, the cited references do not teach or suggest the composition of independent claim 84, as amended, which comprises 20-40%, weight/weight, cartilage enzymatic hydrolysate comprising glycosaminoglycan; 1-10%, weight/weight, grape seed extract comprising oligomeric procyanidol; and 1-10%, weight/weight, tomato extract comprising lycopene.

Accordingly, Applicants submit that the Office Action has not established a *prima facie* case of obviousness and, therefore, Applicants have rebutted the Office Action's rejection of claims 65-69, 73-76, 79, 82-85, and 90-91 based on obviousness. Consequently, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

**CONCLUSION**

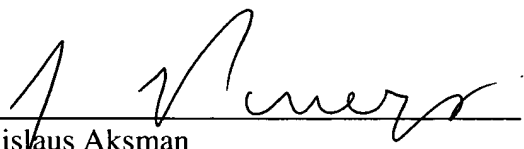
Applicants respectfully request entry of the above claim amendments.

All of the stated grounds of objection and rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

In view of the above claim amendments and remarks, early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their representatives to resolve such issues in an expeditious manner. The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

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